

### **REMARKS**

Claims 2-6, 8-9, 11, 13-14, 16-19, 21-22, 24, 31-33, 35-36 and 73-76 remain in this application. Claims 4, 6, 8, 9, 13, 19, 22, 31, 33, 73, and 75 have been amended to recite “wherein said taste masking agent is comprised of an insoluble film forming polymer” and/or the second layer is comprised of a “water soluble and/or water swellable film forming polymer.” Support for such amendment to the claims can be found in original claim 8 and page 5, lines 17-18. Support for the amendment to claim 36 can be found on page 5, line 29. Accordingly, no issues of new matter are believed to be raised by the above amendments to the claims. Reconsideration of the captioned application as amended herewith is respectfully requested.

### **The Rejection of Claims 2 – 6, 8, 9, 11, 13, 14, 16 – 19, 21, 22, 24, 31 – 33, 35, 36, and 73- 76 under 35 USC §103(a) as Unpatentable Over Maruyama in view of Zingerman, Friend, Abstract, and CA 2068366 Should Be Withdrawn**

Claims 2 – 6, 8, 9, 11, 13, 14, 16 – 19, 21, 22, 24, 31 – 33, 35, 36, and 73- 76 remain rejected under 35 USC §103(a) by Maruyama in view of Zingerman, Friend, CA 2068366, and Norling. Applicants respectfully disagree for the reasons that follow. According to the Office Action,

“prior art discloses a solid preparation containing a first coat ... and a second coat containing a mixture of HPMC and PEG. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose using the ratio of HPMC to PEG of about 80:20 to about 20:80. However, the prior art [allegedly] amply suggest the same....(emphasis added)” See Page 4 of the Office Action

In response to the arguments put forth by Applicants in the previous Amendment, the Office Action on page 5 further states:

“Maruyama does teach that the second coating can be mixtures of agents such as aqueous polymers, such as hydroxypropylmethylcellulose and polyethylene glycol (see col. 6,

lines 23-27). It would have been obvious to one of ordinary skill in the art at the time the invention was made that a combination of the polymers, hydroxypropylmethyl cellulose and polyethylene glycol, could be used as the second coating because the list of possible agents to use as the second coating is fairly limited. Therefore, it would have been obvious to the skilled artisan to try any number of the combinations of polymers to get the desired results. (emphasis added)”

Applicants again respectfully disagree. However, in the interests of furthering this application to allowance, as discussed above, Applicants have amended independent claims 8, 31, 73, and 75 to recite that the particles have two distinct coating layers. As recited in claim 8, the first coating layer is comprised of a taste masking agent that substantially covers the core, wherein said taste masking agent is comprised of an insoluble film forming polymer; and a second coating layer on the surface of the first coating layer, the second coating layer comprised of (i) a water soluble and/or water swellable film forming polymer and (ii) an anti-grit agent selected from the group consisting of polyethylene oxide, polyethylene glycol, and mixtures thereof.

Such particles which comprise a first coating layer having an insoluble film forming polymer and a second coating layer having both a water soluble and/or water swellable film forming polymer and such recited anti-grit agents, are not taught, nor suggested, by the Maruyama et al. alone, or in combination with the other cited references. In fact, Example 5 of Maruyama et al. (an example of a multiple coating layer particle), both lacks an insoluble polymer in the first layer and only has one polymer in the second layer.

Maruyama further fails to offer any justification for using a combination of any of these ingredients at a ratio of “about 20:80 to about 80:20.” Furthermore, Maruyama fails to disclose or suggest oral dosage forms which are “chewable tablets” or “rapidly dissolving tablets” as claimed herein.

As is well founded in the case law, an obviousness determination cannot be based on a “hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention. There must be a teaching or suggestion within the prior art, within the nature of the problem to be solved, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources, to select particular elements, and to combine them as combined by the inventor. When the patented invention is made by combining

known components to achieve a new system, the prior art must provide a suggestion or motivation to make such a combination.” See Crown Operations Intl. Ltd. v. Solutia, 289 F.3d 1367 (Fed. Cir. 2002).

Applicants respectfully submit that one of ordinary skill who reviewed the Maruyama reference would not have been motivated to specifically select a mixture of polymers within the aqueous polymer genus of Maruyama’s granule adhesion preventing agents, nor add such mixture to a coating layer which is coated on a coated particle having a first coating layer comprising an insoluble film forming polymer. Moreover, Applicants further respectfully submit that one of ordinary skill would not have been motivated to specifically select the combination of hydroxypropylmethyl cellulose and polyethylene glycol out of the many species of granule adhesion preventing agents listed and suggested therein, let alone to specifically select such agents at a ratio of “about 20:80 to about 80:20” as claimed herein. Especially given the fact that the components suitable for the second coating layer in Maruyama were used for a completely different purpose (i.e., as “granule adhesion preventing agent[s]”) and not for texture masking of particles as claimed herein, Applicants respectfully maintain that one skilled in the art could not arrive at the present invention without improperly relying upon Applicants’ own Specification in hindsight.

Applicants further respectfully submit that the additional cited art also fails to provide any further suggestion or motivation, alone or in combination, that would teach the use of a second coating layer comprised of the specific combination of anti-grit agents and film forming polymers at the ratio claimed in Applicants’ claimed invention.

As recited in the previous amendment, the other cited art also fails to disclose or suggest the need or the method for modifying the secondary coating of Maruyama, let alone the need or the method for so modifying the “granule adhesion preventing agent” in order to modify it to have a first coating layer is comprised of a taste masking agent that substantially covers the core, wherein said taste masking agent is comprised of an insoluble film forming polymer; and a second coating layer on the surface of the first coating layer, the second coating layer comprised of (i) a water soluble and/or water swellable film forming polymer and (ii) an anti-grit agent selected from the group consisting of polyethylene oxide, polyethylene glycol, and mixtures thereof, as recited in claim 8. Rather, Zingerman is directed to coatings for tablets and not to coating for particles as claimed herein. Friend and the CA 2068366 only exemplify certain

components suitable for tastemasking agents, such as those suitable for Applicants “first coating layer comprised of a taste masking agent.” (emphasis added) The Office Action further found that Norling teaches ingredients for “mask[ing] the bad tasting active substances,” and not coatings for masking texture as claimed.

Therefore, in view of the above, Applicants respectfully submit that the rejection of the claims under 35 USC §103(a) as unpatentable over Maruyama in view of Zingerman, Friend, CA 2068366, and Norling has been overcome and should be withdrawn.

### **Conclusion**

It is submitted that the foregoing amendments and remarks place the case in condition for allowance. A notice to that effect is earnestly solicited.

In the event that all of the claims are not in condition for allowance, Applicants respectfully request for an interview with the Examiner before the preparation of the next Office Action.

Respectfully submitted,

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